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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,278	05/24/2001	Pieter Jacob Swart	702-002214	9397

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EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/720,278	<b>Applicant(s)</b> SWART ET AL.	
	<b>Examiner</b> Roy Teller	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to the election, received 9/27/04, in which applicant elected species bovine lactoferrin and azole compounds, with traverse. The traverse is on the grounds that the groups from which the species elections have been requested are closely knit, homogenous groups that can be readily searched and examined simultaneously. This is not found persuasive because a search for each species is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one species would not necessarily anticipate or even make obvious the other species. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine the numerous species presented in the instant claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-15 and 22 are pending.

### ***Information Disclosure Statement***

The information disclosure statements, received 2/12/01 and 6/15/01, are acknowledged. A signed copy of each is enclosed hereto.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bovine lactoferrin and fluconazole for the treatment of *Candida* does not reasonably provide enablement for a medicament for treatment and/or preventment of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a medicament for treatment and/or preventment of

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infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

The breadth of the claims is excessive with regard to claiming medicament for treatment and/or preventment of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range. Applicant has only provided guidance for the use of bovine lactoferrin and fluconazole for the treatment of *Candida*. Applicant have provided no guidance of any other medicament for treatment and/or preventment of infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

In absence of evidence to the contrary, it would not be expected that any and all polycationic peptides or proteins would act as a medicinal agent. Furthermore, it would not be predictable to the artisan which polycationic peptides or proteins would work in the present invention, nor would it be predictable to the artisan which pathologies could be treated with these polycationic peptides or proteins.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 5, 6, 9, 10, 12, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation followed by linking terms (for example, preferably, maybe, for instance, especially) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired (see MPEP 2173.05(c) for additional information).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 8, 9, 11, 15, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinberg (WO 97/18827).

The claimed invention is drawn to a medicament for treatment and/or prevention of

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infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

Steinberg teaches compositions suitable for treating oral mucositis with antimicrobial peptides comprising a polycationic peptide (lactoferrin) and a buffer (citric acid) which discloses a final pH value of 7.0-7.2. Steinberg discloses vehicle and formulations containing 0.12- 2.0 mg/ ml (see, e.g., for example, page 5, lines 23-34, page 26, lines 9-10, page 37, lines 8-22, page 38, lines 18-22, page 60, lines 19-22, and page 62, claim 1).

Therefore, the reference is deemed to anticipate the instant claims above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 6, 7, 10, 12-14 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakabayashi et al (Antimicrobial agents and chemotherapy, 1998, vol. 42, no. 7, pp.-1587-1591) in view of Steinberg (WO 97/18827).

The claimed invention is drawn to a medicament for treatment and/or prevention of

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infections caused by bacteria, fungi, viri and the like, inflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer for maintaining the pH of treatable tissue within a preselected range.

Wakabayashi beneficially teaches the effects of bovine lactoferrin (LF) coupled with fluconazole to inhibit hyphal growth of *Candida albicans* (see, e.g., for example, abstract, pp-1587 and pp-1589-1590). Wakabayashi does not teach a buffer for maintaining the pH of treatable tissue within a preselected range.

Steinberg beneficially teaches compositions suitable for treating oral mucositis with antimicrobial peptides comprising a polycationic peptide (lactoferrin) and a buffer which discloses a final pH value of 7.0-7.2 (see, e.g., for example, page 5, lines 23-34, page 26, lines 9-10, page 37, lines 8-22, page 38, lines 18-22, and page 62, claim 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have combined the teaching of Wakabayashi effects of bovine lactoferrin (LF) coupled with fluconazole inhibit hyphal growth of *candida albicans* with the beneficial teachings of Steinberg, because Wakabayashi discloses the therapeutic effects of lactoferrin related compounds against candidiasis due to *C. albicans* are now being assessed.

### ***Conclusion***

All claims are rejected.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER